DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

March 15, 2000

Drew Johnson
Director, Regulatory Affairs
Advanced Neuromodulation Systems, Inc.
6501 Windcrest Drive, Suite 100
Plano, TX 75024

Dear Mr. Johnson:

The following is a correction to my February 29, 2000 acknowldgement:

Your petition requesting the Food and Drug Administration to reclassify totally implanted spinal cord stimulator for pain relief from class III to class II was received by this office on 06/16/99. It was assigned docket number 00P-0788/CCP 1 and it was filed on 06/16/99. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Lyle D. Jaffe
Dockets Management Branch

00P-0788

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